

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. DISPOSITION OF THE CLAIMS

Claims 18-21, 29, and 32-33 are pending for examination. Claims 15, 22-27, and 30-31 remain withdrawn.

Applicants thank the Office for withdrawing the rejections under §§ 112 and 103(a).

II. CLAIM REJECTION UNDER 35 U.S.C. § 103

Claims 18-21, 29, and 32-33 stand rejected under 35 U.S.C. § 103(a) as obvious over US 4,876,249 (Rajadhyaksha) in view of US 5,962,482 (Bissett).

A. No Prima Facie Case Of Obviousness Is Established

The Office applied Rajadhyaksha for its disclosure of OX100 in Example 11 as penetration enhancer (see abstract and Example 47, columns 21-22). The Office asserted that Rajadhyaksha discloses that the penetration enhancer may be used with vasodilators (column 12, lines 10-20). See Office Action, page 3, last 2 paragraphs.

The Office conceded that Rajadhyaksha “does not teach the oxazolines as promoting slimming” (Office Action, page 4, line 4). Accordingly, the Office must rely on a second reference, Bissett, to construct a prima facie case of obviousness.

The Office cited new reference Bissett for its disclosure of treating cellulite or reducing localized fatty excesses with niacinamide, disclosed as a vasodilator. Office Action, page 4, third paragraph.

The Office concluded that it would have been obvious to combine Rajadhyaksha’s oxazoline with Bissett’s vasodilator and apply the combination for promoting slimming. Office Action, page 4, lines 2-5 from bottom.

Applicants traverse, because neither Rajadhyaksha nor Bissett nor their combination, suggests Applicants’ discovery that the claimed oxazolines have body slimming activity.

The Federal Circuit recently explained that no *prima facie* case of obviousness is established by references that disclose or suggest:

to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful . . .

In re Kubin, slip op. No. 2008-1184, p. 14 (Fed. Cir. April 3, 2009). Rajadhyaksha's laundry list of vasodilators is an instance of the such an inadequate disclosure. Rajadhyaksha mentions vasodilators in a laundry list of active agents that could be used with the disclosed oxazoline penetration enhancers (column 11, line 50, to column 12, line 20):

The compounds of the present invention are useful as penetration enhancers for a wide range of physiologically active agents and the compositions disclosed herein are useful for topical and transdermal therapeutic effect of these agents. Typically systemically active agents which may be delivered transdermally are therapeutic agents which are sufficiently potent such that they can be delivered through the skin or other membranes to the bloodstream in sufficient quantities to produce the desired therapeutic effect. In general this includes agents in all of the major therapeutic areas including, but not limited to, anti-infectives, such as antibiotics and antiviral agents, analgesics, anorexics, anthelmintics, antiarthritics, antiasthma agents, anticonvulsants, antidepressants, antidiabetic agents, antimigraine preparations, antimotion sickness, antinauseants, antineoplastics, antiparkinsonism drugs, antipruritics, antipsychotics, antipyretics, antispasmodics, including gastrointestinal and urinary; anticholinergics, sympathomimetics, xanthine derivatives, cardiovascular preparations including calcium channel blockers, beta-blockers, antiarrythmics, antihypertensives, diuretics, **vasodilators** including general, coronary, peripheral and cerebral; central nervous system stimulants, cough and cold preparations, decongestants, diagnostics, hormones, hypnotics, immunosuppressives, muscle relaxants, parasympatholytics, parasympathomimetics, sedatives, tranquilizers and anti-osteoporosis agents.

For topical applications the agents include antibiotics, fungistatic and fungicidal agents, corticosteroids, anti-inflammatory agents, antiemetics, antipruritic agents,

vasodilators, bronchodilators, expectorants, analgesics, anti-osteoporosis agents, sunscreen compounds, collagen softening agents and other similar compounds. Cosmetic agents, hair and skin dyes, natural and synthetic hormones, perfumes, insect repellents, diagnostic agents and other such compounds may also be advantageously formulated with these penetration enhancers.

In the passage quoted above, Rajadhyaksha indicates no particular preference for vasodilators. A person of ordinary skill in the art would not have been led to choose vasodilators from this long list of possible active agents to combine with the oxazolines.

The Federal Circuit in *Kubin* also explained that no prima facie case of obviousness is established by references that disclose or suggest:

to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.

In re Kubin, p. 15. Bissett is an example of such a disclosure. Bissett's disclosure that niacinamide is a vasodilator appears in a speculative discussion of how the disclosed invention works (column 2, line 62 et seq.):

Without being bound by theory, niacinamide is believed to reduce cellulite by several mechanisms. Niacinamide stimulates epidermal cells and thus would thicken the tissue to overcome the thinning of the epidermis that is associated with cellulite. These compounds are also vasoactive (stimulate blood flow) and thus would improve the reduction in microvascularization associated with cellulite. Additionally, niacinamide stimulates metabolism in skin cells in general (e.g., epidermis, dermis, subcutaneous fat) which would increase cellular production of the enzymes for turnover or removal of the agglomerations of fatty tissue and/or proteoglycans.

Considering the presently claimed invention as a whole, Rajadhyaksha and Bissett do not make out a prima facie case of obviousness.

B. Unexpected Results Rebut Any Prima Facie Case

Even if a prima facie case of obviousness were made out, the test data in the specification show unexpected results that would overcome such a prima facie case.

Examples 6-7 (pages 18-21) show that the present invention unexpectedly provides inhibition of lipogenesis (see page 20, lines 18-19, and page 21, lines 17-19).

Evidence pertaining to secondary considerations, i.e., unexpected results of the invention, must be taken into account whenever present. M.P.E.P. § 2145, citing *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1372 (Fed. Cir. 2007).

Here, the unexpected results explained above would effectively rebut any *prima facie* case of obviousness made out by Rajadhyaksha and Bissett.

Applicants note that the claims are commensurate in scope with the unexpected results in the specification. Specifically, the present claims are quite narrow in reciting just 6 oxazolines.

For all the reasons presented above, Applicants request withdrawal of this rejection.

III. CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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